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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/313,292

Applicant(s)

WILLIAMS ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87 and 122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16, 17
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other _____

Continuation of Disposition of Claims: Claims pending in the application are 13,15-21,23-29,31-37,39-45,47-53,55-61,63-69,71-77,79-85,87 and 122.

DETAILED ACTION

Priority

1. The claim for priority to provisional applications is in the proper format in view of the amendment received 04 June 2001.

Claim Rejections - 35 USC 101 and 112

2. The rejection of claims 77, 79-84, and newly filed claims 109, 110, and 121 under 35 U.S.C. 101 because the claimed invention lacks patentable utility is maintained for reasons of record in the Office action mailed 01 December 2000. The rejection of claims 61-68 under the same grounds is withdrawn in view of the Declaration under 35 U.S.C. 132 received 04 June 2001 showing preferential expression of SEQ ID NO:1192 in colon cancer cells.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 77, 79-84, and newly filed claims 109, 110, and 121 under 35 U.S.C. 112, first paragraph is maintained for reasons of record in the Office action mailed 01 December 2000. The rejection of claims 61-68 under the same grounds is withdrawn in view of the Declaration under 35 U.S.C. 132 received 04 June 2001 showing preferential expression of SEQ ID NO:1192 in colon cancer cells.

Applicant's arguments filed 04 June 2001 have been fully considered but they are not persuasive. No evidence has been presented that SEQ ID NO:1290 is preferentially expressed in

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any cancer cell. No utility or enablement for use as a diagnostic agent or any other utility is thus apparent for the compositions of claims 77, 79-84, and newly filed claims 109, 110, and 121.

5. The rejection of claims 20, 28, 36, 44, 52, 60, 68, 76, 84, and 92 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention due to a biological deposit that was not perfected in the Office action mailed 01 December 2000 is withdrawn in view of the statement received 04 June 2001 that restrictions on the availability of the deposited strains will be irrevocably removed upon issuance of a patent.

6. The rejection of claims 13, 15-21, 23-29, 31-37, 39-45, 47-53, 55-61, 63-69, 71-77, 79-85, 87-92, and newly filed claims 93-122 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record in the Office action mailed 04 June 2001. This rejection is based on a lack of written description.

Applicant's arguments filed 04 June 2001 have been fully considered but they are not persuasive. Notwithstanding the issuance of U.S. Patent No. 5,861,248, the rejection is maintained as being in compliance with the Office guidelines regarding written description. As there is no indication that the claimed SEQ ID NOS contain a complete open reading frame, the use of open language in the claims causes the claimed invention to read on at least a full open reading frame whose sequence is not described in the instant specification.

Claim Rejections - 35 USC § 102

7. The rejection of claims 77-79, 82, and 84 under 35 U.S.C. 102(a) as being anticipated by GenBank Accession Number AA544005 in the Office action mailed 01 December 2000 is withdrawn in view of the amendment received 04 June 2001.

8. The rejection of sets of claims 13-15, 18, and 20; 21-23, 26, and 28; 29-31, 34, and 36; 37-39, 42, and 44; 45-47, 50, and 52; 53-55, 58, and 60; 61-63, 66, and 68; 69-71, 74, and 76; and 85-87, 90, and 92 under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Numbers M15796, M88458, AA068559, AA131908, A050390, W89528, HSU58766, S82472, and H93085, respectively in the Office action mailed 01 December 2000 is withdrawn in view of the amendment received 04 June 2001.

Claim Rejections - 35 USC § 103

9. The rejection of sets of claims 16, 17, and 19; 24, 25, and 27; 32, 33, and 35; 40, 41, and 43; 48, 49, and 51; 56, 57, and 59; 64, 65, and 67; 72, 73, and 75; 80, 81, and 83; and 88, 89, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Numbers M15796, M88458, AA068559, AA131908, A050390, W89528, HSU58766, S82472, AA544005, and H93085, each in view of Yang et al. in the Office action mailed 01 December 2000 is withdrawn in view of the amendment received 04 June 2001.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

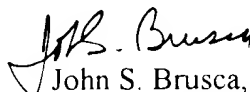
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday -Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-5137 for regular communications and (703) 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


John S. Brusca, Ph.D.
Primary Examiner
Art Unit 1631

jsb
August 24, 2001